

PCT/NL 98/00504

3 Surgical endoscopic cutting device, and method for its use

5 The present invention relates to a surgical endoscopic cutting device according to the preamble of Claim 1.

10 B2 Such a cutting device is generally known and is used for the removal of hard and/or soft tissue, such as in the vicinity of the knee joint. Such a cutting device is used in, for example, a joint cavity, where everything can be guided endoscopically by separately inserting a viewing device consisting of a light source and an observation part. Such operations are successfully used in organs and joints lying not too deep underneath the skin.

15 B3 When operations are being carried out on organs lying deeper down, other techniques are currently used. If, for example, tissue has to be removed from the uterus, prostate or urinary bladder, such as mucous membrane or other parts, it was customary until now to use a so-called loop. This is a loop-shaped cutting wire which is brought to a first potential, while the wall of the uterus is brought to a second, different potential. Tissue is removed by moving the loop along the part of the uterus wall concerned. In order to be able to carry out such an operation, it is necessary to dilate the uterus, and this is carried out by introducing a fluid. In order to maintain the effect of the potential difference, it is necessary for such a fluid not to be current-conducting. An example of this is a 5% sorbitol solution. Because wounds are caused during the treatment described above, a good part of this fluid is resorbed into the patient's bloodstream (by way of the uterus). This can lead to highly dangerous electrolyte displacements. It has been found that the tissue can be removed more easily by working with a high-frequency monopolar electric current, but there is a risk of such a high-frequency electric current leading to internal and external burns. The loop used is generally fitted on a working element with handle on an endoscope, and is moved in a back and forth movement along the uterus wall together with the endoscope. The tissue cut off during this treatment has to be removed separately from the uterus, which considerably extends the duration of the operation, and in addition the doctor has to check that all detached material actually has been removed.

Sub B4 This means that such operations are very time-consuming and require the surgeon to take a large number of steps moving back and forth, which are tiring in the long run and are consequently found difficult to learn. Moreover, the patient has to be monitored continually during the operation, in order to prevent the undesirable phenomena described above. It is not uncommon for such an operation to be broken off because the side effects are such that the patient's life is endangered.

5 On the other hand, it is desirable to be able to carry out such operations instead of simply performing a hysterectomy.

Sub B5 WO 96/11638 discloses a device operating in a machining manner as described above. In this case the cutting means, consisting of a hollow stem and a cutting head, are accommodated inside the rigid housing. This rigid housing likewise contains a viewing channel with the necessary optics. US-A-5,195,541 from which the preamble of claim 1 has been delimited discloses a laposcopic discectomy apparatus. For a laposcopic method it is essential to inflate the related cavity through gas. The gas feed is discontinuous and has no effect on viewing of the operation side.

Sub B6 Fluid is introduced by way of the space between the stem and the rigid housing and discharged together with the detached tissue through the hollow stem of the cutting means.

Sub B7 This device could be satisfactory for the removal of tissues from certain body cavities, such as from the bladder. However, in the case of other body cavities it is necessary to "blow up" the cavity before the treatment can be carried out. An example of this is the uterus, in the case of which it is important that the amount of enlargement of such an organ is accurately controlled. The irregular discharge of fluid through the hollow stem of the cutting means, partly caused by the irregular release of tissue, means that it cannot be guaranteed that the pressure inside the cavity concerned has been accurately controlled.

25 Such a device is consequently not very suitable for use in the treatment of such a cavity.

Ans B8 The object of the present invention is to provide a device by means of which such a treatment is possible after all. This object is achieved in the case of a device of the type described above by the characterizing measures of Claim 1.

2a

*Sub
B9*

By means of the invention a further outlet channel is provided, the function of which channel is independent of whether or not detached tissue has been released. In other words, a regular discharge of fluid can occur by way of this further outlet channel. Since only a minor part of the fluid is now discharged by way of the outlet, in which 5 there are detached pieces of tissue, the pressure inside the body cavity concerned can be regulated and controlled accurately. This makes it possible also to remove undesired tissue from cavities such as the uterus. The application field of the technology for removal of tissues by cutting is consequently considerably increased.

10

15

20

25

30

Sub B10 This further outlet channel described above can be achieved in that an insertion tube is fitted around the endoscopic device. This insertion tube serves to clear a space for the endoscopic device. For this purpose, the insertion tube can be provided at the front side with an insertion mandrel, 5 which is removed after the positioning of the insertion tube and replaced by the endoscopic device described above. In this case the further outlet channel can be defined between the endoscopic device and the insertion tube.

Sub B11 In the case of such a construction it is desirable for coupling means to 10 be present, in order to provide a coupling between the rigid housing and the insertion tube described above.

Sub B12 Discharge of the tissue material which has been detached can be achieved either by making the stem on which the cutting elements are fitted hollow, or by fitting a protective tube surrounding the cutting means. Such a protective tube can also be used without the space between protective tube and stem serving as outlet channel. This means that the cutting means can be 15 designed as a separate unit which can be coupled to the rigid housing, which has advantages in particular in the field of sterilization, for the device according to the invention can then be detached in a particularly 20 simple way.

Sub B13 For the removal of tissue in a uterus it is essential for the rigid housing to have a length which is sufficient to reach all tissue parts, i.e. a length of at least 30 cm.

Sub B14 25 The observation part of the device described above comprises a light channel in the housing, near one end provided with a lens and near the other end provided with observation means. The latter can consist of an eyepiece or a connection for a camera, so that the surgeon can carry out the operation in question using a monitor, and others can possibly look at the same time.

Sub B15 30 The cutting elements described above can comprise all cutting elements known in the prior art. In other words, a cutting head with cutting faces can be used, but it is also possible to use constructions with teeth, meshing with the protective means or otherwise. In the latter instance the protective tube is preferably provided with a lateral opening through which 35 a part of the cutting elements extends, so that on each revolution part of the tissue is removed and can be discharged directly through the interior of the drive/discharge tube of the cutting means.

The invention also relates to a method for the removal of uterus tissue

in which the device described above is used. In other words, a machining operation is now applied with the use of a physiological fluid which can be electrically conducting without any problem, while at the same time the removed tissue is sucked out. It is, of course, possible to suck out the 5 tissue at a later stage. The machining operation is carried out by a rotat- ing action.

Sub B/6 According to a further embodiment of the method, an outlet and a further outlet are present, and the pressure inside the body cavity concerned is regulated by metering the quantity of fluid which moves through that fur- 10 ther outlet. The insertion of the surgical endoscopic cutting device is preferably carried out in the manner described above by means of an inser- tion mandrel and insertion tube.

Sub B/7 The invention will be explained in greater detail below with reference to an exemplary embodiment shown in the drawing, in which:

15 Fig. 1 shows the endoscopic cutting device according to the invention in the assembled state, in side view and partially in section;

Fig. 2 shows the viewing/receiving part of the cutting device according to Fig. 1, in side view and partially in section (Fig. 1a);

20 Fig. 3 shows a device according to Fig. 1 in perspective view, with the insertion end on an enlarged scale;

Fig. 4 shows the cutting means of the cutting device according to Fig. 3, in side view and partially in section;

Fig. 5 shows a detail of a variant of the cutting means shown in Fig. 4; and

25 Fig. 6 shows the insertion mandrel according to the invention.

Sub B/8 The endoscopic cutting device according to the invention is indicated in its entirety by 1 in Fig. 1. It comprises a viewing/receiving part 3, which is shown in Fig. 2, a cutting part 2, which is shown in greater detail in Figs. 4 and 5, and an insertion mandrel, which is shown in Fig. 6.

30 With reference to Fig. 2, it can be seen that the viewing/receiving part 3, is composed of an outer tube 4 in which a main channel 5 and viewing channel 6 are defined. Viewing channel 6 ends at one side in a lens 13 and at the other side in a viewing tube 7, on which an eyepiece or camera connection is placed. A connection 8 for a light source is also present, for 35 connection to a fibre optics bundle which provides for lighting at the end of lens 13. Near the control end, tube 4 is provided with a fluid inlet 9 connected to a hose 12, for adding a physiological salt solution.

A shut-off valve is indicated by 10. (☞ w14)

Sub 19 The distance from the part to be inserted into the patient, i.e. the length of the actual outer tube 4, is indicated by A, and is more than 30 cm.

Sub 5 *Sub 20* Fig. 4 shows details of the cutting means or the cutting part 2, which is composed of a protective tube 16, inside which a drive/suction tube 17 is fitted. Near the working end, tube 17 is provided with teeth 19 which mesh with teeth 18 provided in an opening 26 in the end part of protective tube 16. Near the other end, drive/suction tube 17 is provided with a coupling 20, which can be connected at one end to a rotating drive motor 10 21, not shown in detail, and at the other end is provided with an opening 22 through which fluid and removed material can be discharged by way of suction tube 17 to the discharge hose 23. Pressure-regulating means can be present in this discharge hose 23, which is connected to a vacuum source.

Sub 15 In Fig. 1 the insertion part is also indicated by 27. This insertion part is composed of an insertion tube 28 which is provided with openings 29 and near the end away from the insertion end is provided with a bayonet connection 30 and an outlet 31. Insertion tube 28 is designed in such a way that the rigid housing 4 can be fitted therein, as shown in Figs. 1 and 3, while it is also possible to fit insertion mandrel 40, provided with stem 41 and mandrel 42, in insertion tube 28.

Sub 20 *Sub 22* The construction described above has an inlet 38 for fluid, which inlet extends to channel 14 (Fig. 1a), i.e. the space bounded between the outer tube 4 and the protective tube 16 and 36 respectively from Figs. 4 or 5. A shut-off valve 39 which is connected to channel 14 is present, while the 25 further outlet is indicated by 31. A discharge hose 23 for tissue and fluid is shown. During the removal of tissue, with a substantially continuous supply of fluid through inlet 38 some of the fluid will be discharged through outlet 23. This relatively small amount will be mixed with mixture released during the cutting operation. Most of the fluid will be discharged 30 through the further outlet 31. This discharge is unimpeded and occurs through openings 29. Pressure variations occurring through the presence or absence of removed tissue and through channel 17 (Fig. 4) being shut off or otherwise have little or no influence on the pressure inside the body cavity concerned, owing to the presence of the further outlet 31.

Sub 35 *Sub 23* If the device is to be inserted into, for example, a uterus, insertion mandrel 40 will first be inserted, with shut-off valve 39 open, into insertion tube 28 with bayonet 30. This assembly is then placed in the uterus in a relatively simple manner, through the shape of mandrel 42. Mandrel 42 is

then removed by manipulation on stem 41, and the construction shown in Fig. 2 is placed in tube 28. Connection is made here to bayonet 30. The cutting action can then begin, after the uterus has been dilated first by the introduction of fluid. This fluid can comprise a physiological flushing and 5 distension fluid, such as physiological salt (NaCl 0.9%). In the event of (unavoidable) resorption of these physiological fluids into the blood, electrolyte displacements, with fatal consequences for the patient, will not occur. Owing to the absence of electrical current, the burns described above are also ruled out.

10 By switching on motor 21, tube 17 is set in rotation and teeth 19 move regularly along cutting edge 18 of protective tube 16, which remains stationary. While they are moving along each other and picking up tissue material between them, a cutting/detaching action on the tissue material is occurring, and this material is removed through the interior of tube 17 15 and outlet 23.

The appropriate area of the uterus can be treated by moving parts 18 and 19 along the uterus wall or along tissue to be removed, which can be observed through viewing tube 7 by supplying light through connection 8.

20 Through the use of a continuous flow system, a constantly clear view is obtained for the observer, even if blood and/or mucous is/are in the mixture. Moreover, the pressure can be kept constantly as low as possible, in order to prevent intravasation.

25 Fig. 5 shows a variant of the end of the cutting means. The cutting means or cutting part are indicated in their entirety by 32. The protective tube is indicated by 36 and is bevelled near the end. The drive/suction tube is indicated by 37 and provided with a cutting head near the end. In this embodiment there is either no interaction between cutting head 35 and protective tube 36, or it occurs near the edge of tube 36, which is adapted for that purpose by grinding.

30 It will be understood that such cutting elements can be designed in all ways known in the prior art.

These and further modifications are considered to lie within the scope of the present application and are immediately obvious to the person skilled in the art after reading of the description, and lie within the 35 scope of the appended claims. For instance, it is possible to effect the supply of working fluid and the discharge of cleaning material in another way, i.e. to arrange the interior of housing 4 slightly differently.

Furthermore, the method described above can be used for the removal of

other tissue material, such as prostate tissue through the urethra, or for the removal of tissue from the wall of the urinary bladder.
